

REMARKS

Favorable consideration and allowance are respectfully requested for claims 1-35 in view of the foregoing amendments and the following remarks.

The Examiner is thanked for the careful review and consideration of this case and the notice that the claims contain allowable subject matter is acknowledged with appreciation.

Claim 36 has been canceled without prejudice or any disclaimer of the subject matter therein.

The present restriction of claims into Groups I-XII based on the selection of different R groups is improper and is traversed.

The restriction is traversed because an attempt to restrict within a single claim is improper. The reason it is improper is because such an attempted restriction is in derogation of the applicant's statutory right to define what he regards as his invention and to have each claim examined in its full scope.

An applicant's statutory right to present claims which define a claimed invention in a scope which the applicant regards as his invention is established by the second paragraph of 35 U.S.C. §112. This right was clearly enunciated by the Court of Customs and Patent Appeals in the case of *In re Weber*, 198 USPQ 328 (CCPA 1978). There, Judge Baldwin, writing for the court stated as follows:

An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of Section 112. We have decided in the past that Section 112, second paragraph, which says in part "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention," allows the inventor to claim the invention as he contemplates it. *In re Wolfrum*, 486 F.2d 588, 179 USPQ 620 (CCPA 1973).

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. In re Weber 198 USPQ 328, 331 (CCPA 1978) (emphasis in original).

Thus, the court clearly ruled that an applicant has a right to have each claim examined on its merits in its full scope.

In his concurring opinion, Judge Rich added an elaboration of additional points he wanted to make clear as follows:

The practice here challenged is tantamount to a refusal by the PTO *to examine* a single Markush claim in a single application because, in its opinion, it is *broad* enough to “embrace” or “cover” a plurality of inventions which, if presented separately, would be separately patentable, *assuming* any one of them to be prior art....

The fault in the PTO position is that it overlooks the obvious fact that almost any reasonably broad claim “embraces” or “covers” a multiplicity of inventions, in the sense of “dominating” them, which inventions might be separately patentable if and when presented in separate applications. Logically, this is not a sufficient excuse for refusing to examine a claim on its merits for compliance with 35 USC 101, 102, 103, and 112....

The only justification or statutory authority put forward for refusing to examine is 35 USC 121. There is nothing therein, however, to excuse a refusal to examine an elected invention or an applicant’s generic (broad) claim reading thereon, notwithstanding the generic claim reads on nonelected inventions and possibly many others, all potentially separately patentable....

As for the true meaning of the words “two or more independent and distinct inventions are claimed” in §121, being based -- as they were -- on the “division” practice existing in the then Patent Office in

1952, there can be no doubt they refer to separate inventions separately claimed and to a requirement to put separate claims in separate applications or at least to restrict one application to one claimed invention. There is no indication that enactment of §121 contemplated refusing examination to generic claims because of their scope or that applicants were to be denied the right to present single claims of any breadth they chose and have them examined. *In re Weber* 198 USPQ 328, 333-4 (CCPA 1978) (emphasis in original).

Judge Rich, who himself was one of the authors of the Patent Statute, thus makes it clear that restriction practice was intended to apply between separate claims, but was never intended to deny an applicant the right to have a single claim examined in its full scope.

The Manual of Patent Examining Procedure (the "MPEP"), 8th Edition, U.S. Department of Commerce, Patent and Trademark Office, sets forth the rules of practice related to the restriction of claims involving Markush groups. See § 803.02. In relevant part, the MPEP indicates that "[i]t is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984)." As stated in the Office Action, unity of invention exists where compounds included within a Markush group (1) share a common property, and (2) share a substantial structural feature. The presently pending claims clearly meet this test for unity of invention since (1) all of the compounds have pharmaceutical properties and therefore have a common property in their utility for pharmaceutical applications and (2) all of the compounds share a common base structure (that of formula I). Therefore, these claims share unity of invention and should be examined as written, without any restriction. Further, these rules relating to unity of invention reflect the practice that compounds must be considered as a whole, and not may not be improperly broken down into elements or other components.

The remainder of § 803.02 of the MPEP relates the proper procedure for Examining claims containing Markush groupings which include a plurality of alternatively usable substances or members. The procedures described include requiring a provisional election of species and examining the elected species. If no prior art is found that anticipates or renders obvious the elected species, the search for the Markush claim is extended to the non-elected species to determine patentability of the claim. Thus, even where claims have alternatively usable substances or members, the Markush groupings are examined until one of the groups is determined anticipated or obvious. In the absence of suitable prior art, the claim is allowable.

Not only are Applicants entitled to examination of the presently pending claims because they share a common unity of invention, even for claims with alternatively usable substances or members, the proper practice for examination of Markush groupings is to examine the claims following the guidance provided by an election of species. Thus, the restriction requirement is improper and should be withdrawn.

Applicants therefore respectfully submit that the restriction within a single claim is not justified under Section 121 of the Patent Statute, and is in derogation of applicants' statutory right under Section 112, second paragraph, to claim what they regard as their invention. Reconsideration and withdrawal of the restriction are therefore respectfully requested.

The rejection of claims 35 and 36 under 35 U.S.C. § 112, first paragraph, for lack of enablement, is respectfully traversed. The standard for adequate enablement is whether the specification describes the claimed subject matter in such a way as to enable any person skilled in the art to which it pertains to use the invention. Thus, enablement is judged in view of the combined teachings of the specification and the knowledge of one skilled in the art.

Claim 36 is cancelled, and the rejection thereof is rendered moot.

Claim 35 is directed to a method for inhibiting pain. The Office Action admits that the specification is enabling for treating pain. The comments in the Office Action suggest a belief that the word "inhibit" means completely cure. However, inhibit means only to suppress or reduce. Thus, any pharmaceutical effective to even minimally reduce pain is necessarily effective to inhibit that pain. One cannot effectively treat pain without having some minimal action in lessening that pain. Accordingly, the admission in the Office Action that the specification is enabling for treating pain is necessarily also an admission that the specification is enabling for inhibiting pain.

Further, on page 4, the Office Action incorrectly suggests that a patent applicant must demonstrate the efficacy of pharmaceutical compounds in animal models. This is not the standard for enablement and is not required under U.S. law or practice. The law only requires such a demonstration where there is some reason to not believe the statements in the specification.

The U.S. Court of Customs and Patent Appeals has stated that "The first paragraph of § 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 USPQ 367 , 369 (CCPA 1971). The court also added that "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." *In re Marzocchi*, 169 USPQ 367 , 370 (CCPA 1971). The present record includes no such statement or other explanation as to why the truth of the accuracy of statements in the disclosure should be doubted.

As indicated above, the burden is on the Patent Office to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to

As indicated above, the burden is on the Patent Office to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. On the present record there is no such explanation, and no apparent reason is offered to support the notion that the statements in the specification are not true or accurate.

For the foregoing reasons, a person of skill in the art would be able to practice the claimed invention without further undue experimentation. Accordingly, reconsideration and withdrawal of the rejection of claims under 35 U.S.C. § 112, first paragraph, are respectfully requested.

The rejection of claims 35 and 36 under 35 U.S.C. § 112, first paragraph, as indefinite, is respectfully traversed.

Claim 36 is cancelled, and the rejection thereof is rendered moot.

Claim 35 is amended to reflect that a mammal is being treated. Support for this amendment may be found in the specification, at least, for instance, in the third paragraph on page 8. Accordingly, the entity being treated is specifically identified and to the extent the rejection is based on a lack of such identification it can no longer be upheld.

The Office Action also suggests that the claim must recite some degree of inhibition. In this part of the Office Action, contrary to the language in the enablement rejection, a proper meaning is attributed to the term "inhibit", as it is clear that the term is understood to include less than complete elimination of a condition. However, the rejection is still improper as there is no requirement that the degree of inhibition be defined or assessed. The only requirement in the claim is that there be some inhibitory activity. Thus, the claim language requires only some reduction in pain, regardless of the degree of the reduction.

A person of skill in the art would readily understand this from the claim language. Any inhibition is within the claim. Further, the person of skill in the

art could determine whether or not some reduction of pain is achieved. Therefore the scope of the claim is definite. Reconsideration and withdrawal of this rejection are respectfully requested.

The rejection of claims 14-23, 30 and 31 under 35 U.S.C. § 102(b) as anticipated by Merla (Synlett) is respectfully traversed.

Claim 14 is amended to depend from claim 1. Claim 30 is already dependent from claim 1 (through claim 5). Thus, the rejected claims include all of the limitations of claim 1, including the proviso of claim 1. Therefore, the rejected claims are directed to methods that result in the production of compounds falling within claim 1.

Merla relates to compounds outside the scope of claim 1. The reference does not teach compounds within claim 1, or methods of making such compounds. The morpholine compound identified in the Office Action (formula 4) and the dipyrrole compound (formula 3) are both excluded from claim 1 by the proviso therein. Accordingly, the reference does not teach each and every element of the claims and the rejection cannot be properly maintained.

Reconsideration and withdrawal thereof are respectfully requested.

The objection to the claims as containing non-elected subject matter is traversed and the comments above addressing the restriction requirement are applicable to this objection. Reconsideration and withdrawal of the restriction requirement and the associated objection to the claims are respectfully requested in view of these comments.

CONCLUSION

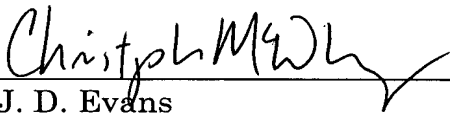
In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #029310.52539US).

Respectfully submitted,

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